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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,250	02/01/2001	David Berd	1225/1G584US2	8162

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EXAMINER
CANELLA, KAREN A

ART UNIT	PAPER NUMBER
1642	9

DATE MAILED: 04/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/776,250	Berd
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-24* _____ is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *21-24* _____ is/are allowed.

6) ☒ Claim(s) *1-20* _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Claims 1-24 are pending and examined on the merits.

Information Disclosure Statement

2. The IDS filed June 6, 2001 has been considered. However, the PTO form 1449 listing the references was not enclosed with the submitted references. Applicant is invited to provided a copy of the PTO-1449 listing the submitted references.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) The recitation of "cyclophosphamide" in claim 16 lacks proper antecedent basis in claim 14.

(B) The recitation of "the method" in claims 12-14, 16 and 17-20 lacks proper antecedent basis in claim 10, as claim 10 is drawn to a composition, not a method.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 6 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al (PNAS, 1971, Vol. 68, pp. 469-472). Claim 1 is drawn in part to a composition comprising haptenized tumor cells comprising from about 2 X 10^5 to 2.5 X 10^6 tumor cells per dose, wherein the tumor cells are conjugated to a hapten and rendered incapable of growth in vivo. Claim 2 is drawn in part to dinitrophenyl as the hapten of claim 1. Claim 3 specifically embodies the hapten of dinitrophenyl. Claim 6 is drawn in part to leukemia cells as the tumor cell of claim 1. Claim 9 specifies that the tumor cells have been rendered incapable of growth by irradiation. Claim 10 specifies that the composition of claim 1 is free of adjuvant.

Claim 11 is drawn in part to a method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to said patient a composition comprising haptenized tumor cells from about 2 X 10^5 to 2.5 X 10^6 tumor cells per dose, wherein the tumor cells are conjugated to a hapten, and rendered incapable of growth in vivo. Claim 12 specifies the method of claim 11, wherein a first dose of the composition is administered without adjuvant.

Martin et al disclose a method of inducing an anti-tumor response in mice comprising the administration of a composition consisting of 5 X 10^5 EL-4 leukemia cells (page 469, second column under "Immunization"), wherein said cells have been irradiated with 1500 Rads rendering them incapable of growth in vivo and haptenized with 2,4-dinitrophenylaminocaproate (page 469, second column under "Chemical coating of tumor cells).

7. Claims 1-3, 6, 7, 9, 11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Berd et al (Ann NY Academy Sci, 1993, Vol. 690, pp. 147-152).

The embodiments of claims 1-3, and 9 are recited above. Claim 7 specifies the tumor as a melanoma cell. Claim 15, depending on claim 11, specifically embodies the administration of the claimed composition prior to the administration of cyclophosphamide.

Berd et al disclose a method of inducing an anti-tumor response in a human patient comprising the administration of 1 X 10^7 to 12 X 10^7 autologous, irradiated (2500 rads)

dinitrophenyl conjugated melanoma cells. Twenty eight days later, cyclophosphamide was administered, fulfilling the requirement of administering the composition prior to the administration of cyclophosphamide. The instant claim is drawn to a method and a composition comprising 2 X 10^5 to 2.5 X 10^6 irradiated, haptenized tumor cells which reads on compositions comprising a greater number of cells.

8. Claims 1, 2, 6, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujiwara et al (the Journal of Immunology, 1980, Vol. 124, pp. 863-869).

The embodiments of claims 1, 6, 9 and 10 are listed above. Claim 2 is drawn in part to the hapten of trinitrophenyl.

Fujiwara et al disclose a composition consisting of 10^5 irradiated, TNP conjugate LSTRA cells, which are leukemia cells (page 864, first column, under "In vitro sensitization for cytotoxic effects").

9. Claims 1-3, 6-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Berd et al (WO 98/14206, reference 10 of the IDS filed June 6, 2001).

Claim 1 is drawn in part to a composition comprising haptenized tumor cells comprising from about 2 X 10^5 to 2.5 X 10^6 tumor cells per dose, wherein the tumor cells are conjugated to a hapten and rendered incapable of growth in vivo. Claim 2 is drawn to a list of haptens. Claim 3 specifically embodies the hapten of dinitrophenyl. Claim 6 is drawn to cancers selected from the group consisting of: melanoma, ovarian cancer, breast cancer, colon cancer, rectal cancer, lung cancer, kidney cancer, prostate cancer, and leukemia as the tumor cell of claim 1. Claim 7 specifically embodies melanoma. Claim 8 specifically embodies ovarian cancer. Claim 9 specifies that the tumor cells have been rendered incapable of growth by irradiation. Claim 10 specifies that the composition of claim 1 is free of adjuvant.

Claim 11 is drawn in part to a method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to said patient a

composition comprising haptenized tumor cells from about 2 X 10^5 to 2.5 X 10^6 tumor cells per dose, wherein the tumor cells are conjugated to a hapten, and rendered incapable of growth in vivo. Claim 12 specifies the method of claim 11, wherein a first dose of the composition is administered without adjuvant.

Berd et al disclose a method of treating a patient suffering from melanoma, ovarian cancer, breast cancer, colon cancer, rectal cancer, lung cancer, kidney cancer, prostate cancer, or leukemia (page 6, lines 21-30) comprising the administration of a composition comprising 2 X 10^5 to 2.5 X 10^7 irradiated (page 8, lines 25-29), haptenized (page 9, lines 3-25) tumor cells. The instant claims are drawn to cell compositions comprising 2 X 10^5 to 2.5 X 10^6 tumor cells which falls within the disclosed range of 2 X 10^5 to 2.5 X 10^7.

10. Claims 1-7 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Berd et al (WO 96/40173, reference 11 of the IDS filed June 6, 2001).

Claim 1 is drawn in part to a composition comprising haptenized tumor cell extract comprising about 2 X 10^5 to 2.5 X 10^6 tumor cell equivalents per dose, wherein said cell equivalents are conjugated to a hapten and rendered incapable of growth in vivo. Claim 2 is drawn in part to dinitrophenyl as the hapten of claim 1. Claim 3 specifically embodies the hapten of dinitrophenyl. Claim 4 specifies that the tumor cell extract comprises tumor cell membrane components. Claim 5, dependent upon claim 4, specifically embodies the tumor cell extract, wherein said extract comprises tumor cell polypeptides. Claim 6 is drawn in part to tumor cell extracts originating from a tumor selected from the group consisting of melanoma, breast, lung, colon, kidney and prostate cancer. Claim 9 specifies that the tumor cells have been rendered incapable of growth by irradiation. Claim 10 specifies that the composition of claim 1 is free of adjuvant.

Claim 11 is drawn to a method of inducing an anti-tumor response in a patient suffering from a tumor, which method comprises administering to a patient a composition comprising administering a composition of tumor cell extract comprising about 2 X 10^5 to 2.5 X 10^6 tumor

cell equivalents per dose, wherein the tumor cell equivalents are conjugated to a hapten and rendered incapable of growth in vivo.

Berd et al disclose a method of treating melanoma, breast, lung, colon, kidney and prostate cancer comprising the administration of tumor cell or tumor cell extract, wherein said tumor cell extract may be haptenized or irradiated prior to administration. Berd et al disclose a composition consisting of 5 X 10 6 haptenized, irradiated tumor cells. Berd et al further disclose that cancer cells of a patient may be conjugated to a hapten, followed by isolation of membranes (page 25, lines 1-4), therefore, Berd et al disclose cell extracts comprising 2 X 10^5 to 2.5 X 10^6 cell equivalents per dose. Berd et la disclose that the tumor cell extract comprises tumor cell polypeptides as tumor cell peptide may be extracted from haptenized cells (page 26, lines 19-24).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper tames extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.d. 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-3, 6-9 and 11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 8, 9, 10 of copending Application No. 09/304,859. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of inducing an anti-tumor response comprising the administration to a patient in need thereof a "therapeutically effective" amount of a tumor cell or tumor cell extract embodies the instant claims drawn to a composition and a method as the '859 application discloses a therapeutically effective amount of haptenized, irradiated tumor cell or tumor cell extract as containing 105 cell or cell equivalents per dose (page 15, lines 25-31).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1-3, 6-9 and 11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 7, 11, 16, 20, 21, 25, 53, 54 and 55 of copending Application No. 09/025,012. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '012 application both claims and teaches therapeutically effective amounts of haptenized tumor cell equivalents of 10^4 to 7.5 X 10^6 as well as 2.4 X 10^6 to 7.5 X 10^6 cell equivalents per dose for the treatment of a variety of solid and non solid malignancies as listed on page 18, lines 1-17 of the '012 application).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
April 7, 2002